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K001669

XIII. SAFE MEDICAL DEVICES SUMMARY OF SAFETY AND EFFECTIVENESS
(Separate Page)

A. Submitter: Joseph McTernan, Hanger Orthopedic Group, Inc., Bethesda, Maryland; Phone 301-280-4528.

I. Classification: Class II.

II. Common or usual name: cranial orthosis

III. Proprietary Name: Hanger Cranial Band™

IV. Registration No.: 1056769

V. Classification Name: Cranial Orthosis, Code MVA, CFR 882.5970

VI. Performance standards: None, Special Controls required.

VII. Description: The Hanger Cranial Band™ is a thermoplastic helmet consisting of a semi-rigid outer shell fitted with a medium density foam inner lining. This device is fabricated from a plaster of paris impression taken of the infant's head. This impression is filled with a plaster slurry to create a positive mold. The deformity is corrected to the desired configuration with the onlay of molding material. This corrected mold serves as a template for the Hanger Cranial Band™ fabrication. The completed Hanger Cranial Band™ applies gentle pressure to the elevated areas of the skull while leaving space for cranial growth in the depressed regions.

VIII. Labels and Labeling: Labels and Instructions for Use are provided including precautions, and materials required by the special controls to which this product is subject.

IX. Instructions for Use: For treatment of positional plagiocephaly.

X. Substantial Equivalence: The Hanger Headband™ is substantially equivalent to the device classified recently (FR. Vol. 63, No. 146, July 30, 1998, pp. 40650-52) and to the DOC Band™ cleared by Cranial Technologies, Inc., in K-964992.

The "510(k) Substantial Equivalence Decision-making Process (Detailed) from ODE Guidance Memorandum #86-3 was followed.

XI. Clinical Discussion and Literature: A comprehensive review of the literature was provided.

(End of Summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Joseph McTernan
Director Regulatory Affairs
Hanger Orthopedic Group, Inc.
2 Bethesda Metro Center
Bethesda, Maryland 20814

Re: K001669
Trade Name: Hanger Cranial Band
Regulatory Class: II
Product Code: MVA
Dated: September 11, 2000
Received: September 15, 2000

Dear Mr. McTernan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

X. Indications for Use: [Separate Page]

510(k) Number: NA

Device Name: Hanger Cranial Band™

Indications for Use:

Intended for medical purposes to apply pressure to prominent regions of an infant's cranium to improve cranial symmetry or shape. To treat infants from three to eighteen months of age with moderate to severe non-synostotic positional plagiocephaly, including plagiocephalic-, brachycephalic-, scaphocephalic-shaped heads.

Contraindications for use: Infants with synostosis or hydrocephalus.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Mark N Milhous

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001669